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French child cohort study (Elfe)

***Explanatory document for the
in-home survey at age 3.5 years***

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1 Context, objectives and general organization

The survey at 3.5 years was conducted in two stages:

- a questionnaire administered by phone;
- a home visit for a study sub-sample.

The purpose of the home visit was:

- to **collect information directly from the child;**
- to collect **non-invasive biological samples: exclusively from families who gave biological samples at the maternity unit;**
- to collect **environmental samples: exclusively from a sub-group selected at random from households that gave urine and hair samples at the maternity unit, with a target of 1,000 participating households;**
- to fit the child with an accelerometer to be worn for 7 days and nights, depending on the availability of the 73 Actigraph GT3X accelerometers (movement detectors) purchased for the study.

The families were initially contacted for the phone interview. During this phone call they were asked to agree to take part in the in-home survey, about which they had already been informed in writing. Consequently, only families successfully contacted for the phone survey were eligible for the home visit (see Section 4). For cost reasons, the maximum number of home visits was set at 10,200, so not all families were initially eligible for the home visit. For waves 1 and 2 (children born in April and in June-July), the eligible families were randomly selected. However, families with twins and those which gave biological samples in the maternity unit had an inclusion probability of 1. For the other families, an unequal selection probability, the inverse of the maternity unit weighting, was used in order to over-represent the least socially advantaged families. The selection methodology is given in Appendix 5.1. This sampling method was dropped for waves 3 and 4 (children born in September-October and in December due to the lower-than-expected rate of consent for the phone interview which limited the number of families eligible for the home visit.

The files used to provide interviewers with the contact details of the families to be visited were separate from those used to collect data. For the various home visit documents (CAPI [computer assisted personal interview] questionnaire, tests performed with child, administrative documents, paper form to identify the samples and accelerometers) the children were identified with a number followed by three letters of their first name for ex-post error checks.

Specific information was given and specific consent was required for the accelerometer study and for biological and environmental sample collection. The corresponding documents are reproduced in Appendices 5.3 to 5.9.

2 Organization of the home visit

One of the parents, or a person authorized by the parents, was present with the child(ren) during the visit, which proceeded as follows:

- Saying hello, setting up: 5 min
- Drawing done by the child: 5 min
- Cognitive test with child followed by vision tests: explaining, testing: 20 min
- Explaining about biological samples: 5 min (sub-group)
- Environmental samples: 25 min (sub-group)
- Explaining how to remove and send back the accelerometer: 5 min (sub-group of families without twins, depending on availability of the 73 accelerometers)
- Completion of a questionnaire by the interviewer: 5 min
- Packing up, saying goodbye: 5 min

TOTAL: 40 to 70 min

For twins, the vision and cognitive tests and the drawings were done by each child separately while the other child was in another room.

3 Content of the home visit

3.1 Drawing

The child was asked to draw a man on a sheet of white unlined A4 paper presented in portrait format (vertical). No time limit was imposed (5 minutes was considered to be long enough at this age).

*“You are going to draw a picture of a man on this sheet of paper. **Draw me a nice picture and take your time.**”*

If the child had his/her own colour crayons or felt pens, s/he could use them to draw the picture. S/he was not allowed to use an eraser. The picture had to be drawn from memory, with no visible model that the child could copy. On the back of the sheet, the interviewer recorded the child’s age in years and months, their gender and the hand used (left/right) to draw the picture.

If the child refused to draw the picture at the start of the visit, the interviewer asked him/her again after the vision tests.

A system based on the Goodenough scale¹ was devised by a specialized team to give a development score for each drawing. It will be made available to all interested researchers after a period of exclusivity.

¹ Goodenough, F.L. and D.B. Harris, Studies in the psychology of children's drawings: II 1928-1949. Psychol Bull, 1950. 47(5): pp. 369-433.

3.2 Test of child's cognitive capacities: BAS "Picture similarities"

The "Picture similarities" module of the "British Ability Scale"² was chosen because it satisfies a set of practical criteria:

- The game is played by an interviewer with no medical training and who does not normally work with young children;
- The rules of the game are simple, so the interviewer has to give very few instructions to the child;
- The child's answers are scored automatically and unambiguously, making the system easy to use for interviewers;
- The rules for stopping the game are completely automatic and do not need to be decided by the interviewer;
- The game is short, to take account of the child's attention span and to respect the parents' private life by limiting the time spent in their home.

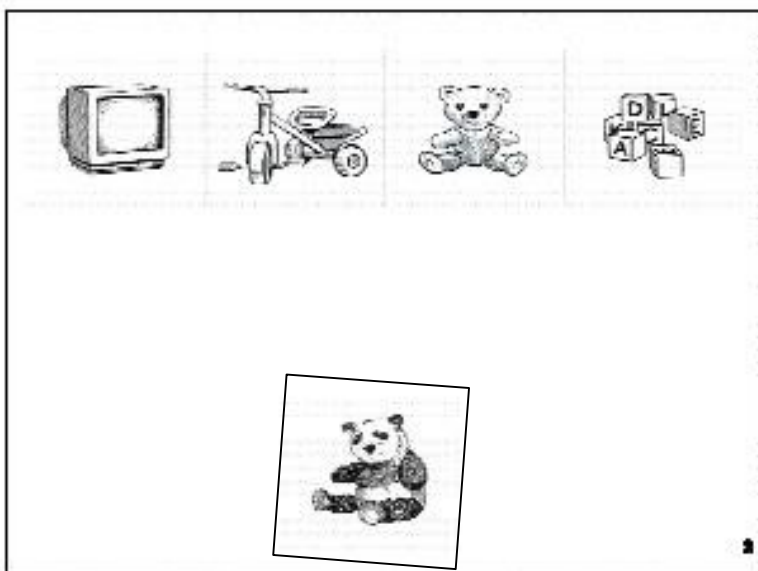
The British Ability Scale is internationally recognized and has already been used, for example, in the Millennium Cohort Study at age 3 (Naming Vocabulary scale) and at age 5 (BAS).

According to the BAS developers, the "Picture Similarities" module tests the child's abilities in:

- Non-verbal problem solving (inductive reasoning)
- Visual perception and analysis
- Attaching meaning to pictures
- Developing and testing hypotheses
- Use of verbal mediation.

Low scores may also reflect impulsiveness (answering without checking the answer).

The game comprises a set of 33 cards and 33 successive sets of 4 images. The rules for stopping the game are based on the responses entered directly into the computer by the interviewer.



Each set of 4 images is shown to the child in succession, along with a card showing a 5th image.

The child must indicate which image on the page shares an element or concept with the card ("which one fits best"), by placing the card under one of the four images on the page, for example. The first 5 pages are practice pages. The test ends when the child has made 6 errors on 8 consecutive pages.

Example of practice game:

"Here is a set of pictures: the card (at the bottom) goes with the third picture because both are pictures of soft toys."

² Elliott CD, Smith P., McCulloch K., British Ability Scales Second Edition (BAS II): technical manual. London: NFER-Nelson, 1997.

The children's test scores were calculated using the method described in the BAS manual and are available for consultation (see Appendix 5.2).

3.3 Vision tests

A child with poor visual acuity may give wrong answers to the cognitive test, resulting in an inaccurate assessment of his/her cognitive abilities. At the same time, visual attention and the ability to analyse, understand and memorize images may vary from one child to another, independently of their visual acuity.

The cognitive test was therefore combined with:

- a near vision test
- a test of the child's ability to fix his/her gaze
- an analysis of superimposed images
- a test of the child's ability to form a shape with their hands in imitation of the interviewer so as to detect any dyspraxia (impaired ability to imitate a shape with one's hands)

A booklet of the various vision tests (see Appendix to the face-to-face questionnaire at age 3.5 years) was shown to the child by the interviewer sitting by his/her side:

- For the near vision test, performed for each eye separately (eyepatch used), the interviewer showed the child a series of pages displaying images of steadily decreasing size and asked him/her to name them or point to the matching image on a page showing all of the six possible images. Children who wear glasses performed the test with and without glasses, on different sets of pages to avoid memory bias.



- After this first game ended, the interviewer asked the child to do a praxis test by making a shape with their hands (figure shown opposite: see coding instructions in the 3.5 year face-to-face questionnaire), then a test of his/her ability to fix the gaze, asking the child to fix for 10 seconds, without moving either the eyes or the head, the end of a pencil held by the interviewer.



- The vision tests end with a test to decipher the superimposed image shown opposite: "What can you see in this picture". Responses that were phonologically or semantically close to the correct answers were accepted (bowl for bucket, felt pen for crayon, etc.).

3.4 Objective measure of physical activity and sleep quality

Body movements are recorded using an accelerometer, a simple small appliance containing a piezoelectric motion sensor. It provides an objective measure of the frequency and duration of physical activity at different levels of intensity (low, medium, high) and of the overall amount of time spent on sedentary activities. It also records the frequency of “breaks” (active interludes) occurring in sedentary periods. Accelerometers are also used to measure quantity of sleep (daytime and night-time) and its quality (number and duration of wakeful periods based on movements recorded during periods identified as spells of sleep by combining information from the accelerometer and the parental questionnaire).

If the parents gave their consent during the telephone survey, and if an accelerometer was available, it was initialized at the INED Elfe unit then sent to the families early enough to ensure that the 7 successive days of recordings could be completed before the interviewer’s visit. The accelerometers were recovered by the interviewers during the home visits and sent back by post to INED where the data recordings were downloaded.

The Actigraph GT3X-BT appliances were worn by the Elfe children on their waists to measure their physical activity and sleep. They were delivered with an explanatory letter for the parents, a consent form and a letter for the nursery school teacher to ensure that it was not removed in class. The child was asked to wear the appliance night and day for 7 consecutive days. If the child was happy to wear the appliance, the parents were asked to remove it only when the child was taking a bath or shower.

The appliance was sent with a questionnaire to record the times when the child went to bed, woke up at night, woke up in the morning, started and ended his/her afternoon nap, took off the appliance (bath time, swimming pool, etc.). All documents sent to the parents are given in Appendices 5.3 to 5.6.

3.5 Biological samples

After receiving the relevant information, eligible families gave their informed consent for biological sample taking on a form signed by at least one parent (Appendix 5.8) that was collected by the interviewer. The interviewer checked that the biological samples had already been taken and returned by post to the Elfe biobank. If this was not the case, the parents were reminded to take the samples within the next few days.

The collection, shipment and processing of the various biological samples are described below.

3.5.1 Urine

In addition to environmental exposures, the presence of a wide range of molecules (markers of renal function and hormone secretion, molecules produced by the metabolic breakdown of drugs, nutrients, etc.) can be measured in urine. However, the conditions of in-home sample collection and shipment must be taken into account before going ahead with urine sample analysis.

The entire volume of the child’s first miction was collected directly in a bottle. The sample was stored in the family’s refrigerator (between +4 and +10°C) before shipment to the biobanks.

3.5.2 Hair

A sample of the child's hair was taken by one of the parents using the established procedure. The hair sample was attached to a card using a paper clip supplied for this purpose and placed in the envelope.

3.5.3 Stools

A stool sample was taken from 3,000 newborn Elfe infants in their first days of life. For a sub-group of 700 of these children, a further sample was taken at between 12 and 18 months.

A stool sample at age 3.5 years was first requested from children who had already given a stool sample at birth and who were still in the Elfe cohort. Due to a delay in the delivery of sample tubes, the stool sampling operation did not begin until 23 February 2015. From 1 June 2015, all families involved in the biological survey module were asked to provide stool samples.

The stool samples were collected with an Entérome kit using a spatula that was screwed into a tube filled with stabilizing fluid once the sample had been taken. The tube was stored in the refrigerator before shipment to the biobanks.

3.5.4 Sample shipment and storage

A sample information form completed by the family was enclosed with the samples to guarantee their traceability (see Appendix 5.7).

This form also included information on the times of day when the child had urinated before the urine sample was taken, the composition and type of food eaten at the evening meal and its preparation method, and the personal hygiene products used the evening before the urine sample was taken.

All samples were placed in special containers for biological product shipment supplied by the Elfe team and then sent in a box to one of the three Elfe biobanks (EFS biobanks at Annemasse, Bois-Guillaume or Dijon, depending on where the family's maternity unit samples were stored). After reception and quality control, the urine and stool samples were aliquoted and stored at -80°C . The envelope containing the lock of hair was stored at ambient temperature.

3.6 Environmental samples

Dust samples were collected in the homes of a sub-sample of families by taking the contents of the family's vacuum cleaner and wiping cloths over the floor using a specific procedure taught to interviewers to ensure its reproducibility and comparability (see Appendix 5.9).

A questionnaire was completed to indicate the type of dust collected (rooms vacuumed, outside or not, garage, fireplace, DIY waste, etc.) the dwelling characteristics and the modes of ventilation (see face-to-face questionnaire, 3.5 years).

4 Rates of consent and participation

Among the 11,453 families that responded to the telephone survey and were eligible for the home visit, 89% gave their consent and 81% (9,293) took part.

Among the sub-samples eligible for specific modules, the table below gives the numbers of families invited to take part in the module and those that actually took part, either fully or partially.

	Biological samples	Dust samples	Accelerometry
Invited	3 415	1 035	4 519
Took part	2 125	837	463*

*For the accelerometry module, 2,930 of the 4,519 families agreed in principle, but due to the limited number of appliances available, only 595 families received one and only 463 children were able to wear it for at least one whole day. The other families that had given their consent were informed by mail that no appliance was available.

5 Appendices

5.1 Sampling methodology for home visit eligibility

Sampling was performed in two phases: on waves 1 and 2, then on waves 3 and 4. Proportionally to each wave, the aim was to obtain 4,121 children in the first two waves and 6,079 in the following ones.

The following requirements were defined for the sample:

- All children whose family provided biological samples (variable ECHBIO) and all twins (M00M1_NAISGEM) are systematically included in the sample.
- A subset of families unlikely to consent to take part is defined by an ineligibility criterion (variable IND_3A5). They cannot be selected in this sample³.
- For the selection process to obtain the desired sample size, the probabilities will be unequal and proportional to the child-level weights of individuals defined in the maternity unit (M00E_PONDVAL).

Sampling on waves 1 and 2

To maintain the same inference population as in the previous surveys, the ineligible individuals are treated as a non-response phase. They form part of the sampling frame with a non-zero inclusion probability, and are then removed from the selection after being identified. The selection process anticipates and compensates for this loss, estimated at around 13%.

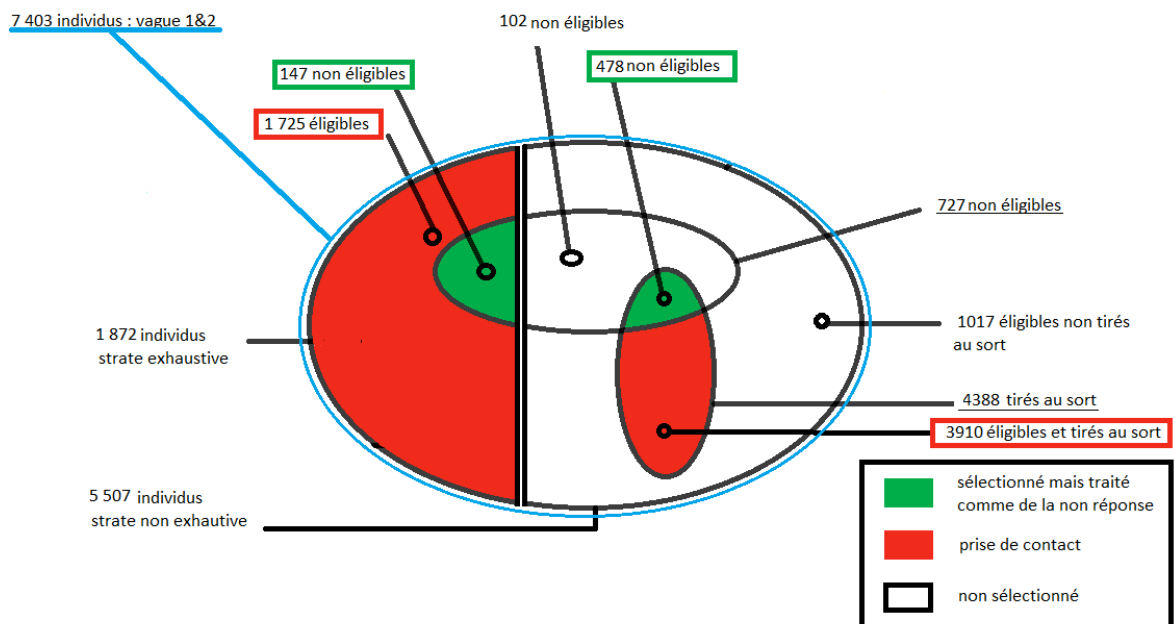
The non-response phase (real this time) is also anticipated using data from the pilot survey. It is estimated at 25%, taking account of expected differences between the pilot and the survey.

An exhaustive selection stratum is thus established, comprising children whose family provided biological samples and twins (1,872 children in total, of whom 1,725 are eligible), alongside a stratum with a selection probability proportional to weight (5,507 children). The sample is selected using the SAS survey select procedure (pps method).

The STRATEPRELJUM35 variable references the entire exhaustive stratum, whether eligible or not. And the TIREAUSORT35 variable references all selected individuals, either from the exhaustive stratum (probability of 1) or in the non-exhaustive stratum (variable probability), whether eligible or not. The IND_3A5 variable is retained to indicate whether the individual is eligible or not.

Hence, among the 7,403 individuals of the first two waves, 5,635 were selected to be contacted at age 3.5 years, SELECTION35 variable. This group included 210 twins and 1,557 children whose family gave biological samples; 43 individuals were defined as eligible for selection but had a remark about their situation: they were assumed to be outside metropolitan France at the time of the survey, or had notified their refusal to take part by phone. Given the uncertainty, and to avoid assuming that they would not participate, they were kept in the sampling pool, and 33 were finally selected. The selection principle and results are represented in the diagram below. The diagram is not proportional and the 24 individuals born outside the 25 days of inclusion are not represented. (Exhaustive stratum + non-exhaustive stratum + 24 = Waves 1&2).

³ The families that had not taken part since the maternity unit survey were excluded, along with families that refused to take part in the survey at both 1 year and 2 years without doing the non-respondent survey at 2 years, or who dropped out or refused to take part in these same two surveys without doing the non-respondent survey at 2 years.



The differences between the selected sample and the non-selected eligible individuals can be compared for several sociodemographic variables. For each of these variables, the distribution differences between the two populations are significant at 5%. The tables below give the percentages of each category in the two sub-populations (selected to be contacted or not) among eligible individuals (6,676 children). We see (first table, first column) that 0.1% of mothers are farmers in the non-selected group versus 0.43% in the selected group. The sum of each column totals 100%.

<i>Variable CSP1</i>	Occupational category mother		Occupational category father	
	Non-Selected	Selected	Non-Selected	Selected
Farmer	0,1	0,43	1,28	1,74
Self-employed	3,15	3,18	8,06	8,82
Higher-level occupation	30,38	16,72	29,3	22,73
Intermediate occupation	23,7	20,62	14,95	13,24
Clerical/sales worker	40,51	48,13	32,25	34,2
Manual worker	1,97	4,12	11,5	14,02
Economically inactive	0	2,73	0	0,21
Student	0,1	0,83	0,69	0,71
Occupation cannot be classified	0,1	3,25	1,97	4,33

<i>Variable LIEUNAIS</i>	Mother's place of birth		Father's place of birth	
	Non-Selected	Selected	Non-Selected	Selected
In France	91,67	86,18	88,8	85,39
In another country	8,33	13,82	11,2	14,61

<i>Variable ETATMAT</i>	Non-Selected	Selected
Married or remarried (including legally separated)	49,95	46,37
Civil partnership (PACS)	16,55	15,12
Divorced	0,7	1,26
Single	32,8	37,1
Widowed	0	0,15

The mean weight in the selected sample (exhaustive stratum included) is 45.7 (versus 24.2 in the non-selected population). This difference, calculated for both eligible and non-eligible individuals as both are concerned by the selection, is the desired characteristic of selection proportional to weight. High weights took precedence in this case, meaning that populations that are difficult to recruit or retain in the survey are over-represented in the selected sample. For a given sub-sample size, while maintaining the random nature of selection, the survey concentrates on poorly represented populations, anticipating their non-response and thereby improving the statistical quality of the sub-sample over the long term.

Sampling on waves 3 and 4

In light of the experience of waves 1 and 2, all families in waves 3 and 4 were eligible for the in-home survey.

5.2 Rules for calculating British Ability Scales Picture Similarities Test scores

Preamble

The programmed stopping rule that applies to all children whatever their age is as follows: the test is stopped when the child make 6 errors on 8 consecutive pages.

The practice pages are counted in the score.

1. First stage: calculating the raw score:

All correct responses are simply summed (1 point per correct answer, otherwise 0).

However, **the child's age and success rate on an initial number of pages must be taken into account to calculate the test score.** Refer to the "item set" reference table in the manual (score calculated out of 23, 28 or 33 depending on the theoretical maximum number of pages shown to the child).

The general BAS rules are as follows:

Ages	Starting	Decision
2:6 -- 3:5	Item 1	Item 23
3:6 -- 4:5	Item 1	Item 28
4:6 -- 7:11	Item 11	Item 33

"Decision point" = STOP unless < 3 errors on all items shown to child; the test continues until the next "Decision point".

In Elfe, on the other hand:

- **The "Decision points" are not programmed;** only the rule of 6 errors on 8 consecutive items is applied to stop the test, as mentioned above;
- **none of the children were more than 4 years 5 months old at the time of the test**

The score calculation program thus takes account of the two following situations:

- *situation 1: the child is between 3 years 6 months old and 4 years 5 months old.*

- a. the score is <26 on the first 28 pages

Either the child made 6 errors on 8 consecutive items and the test stopped before page 28;

Or the child made 3 or more errors (but not 6 on 8 consecutive items) on the first 28 pages and the test continued up to page 33 (whereas the test would have been stopped in the original version).

The score is calculated out of 28, i.e. by selecting the item set 1-28.

b. the score is ≥ 26 on the first 28 pages

The child made fewer than 3 errors on the first 28 pages (0, 1 or 2 errors), the test continued in accordance with the rules of the original version and 5 additional pages were shown to the child, making 33 in all.

The score is calculated out of 33, i.e. by selecting the item set 1-33.

- *situation 2: the child is below 3 years 6 months old.*

a. the score is < 21 on the first 23 pages

Either the child made 6 errors on 8 consecutive items and the test stopped before page 23;
Or the child made 3 or more errors (but not 6 on 8 consecutive items) on the first 23 pages and the test continued (whereas the test would have been stopped in the original version).

The score is calculated out of 23, i.e. by selecting the item set 1-23.

b. the score is ≥ 21 on the first 23 pages

The child made fewer than 3 errors on the first 23 pages (0, 1 or 2 errors), the test continued and 5 additional pages were shown to the child.

Again, after page 28:

Either the child made fewer than 3 errors on the first 28 pages and the test continued up to page 33:

The score is calculated out of 33, i.e. by selecting the item set 1-33.

Or the child made 3 or more errors (but not 6 on 8 consecutive items) on the first 28 pages and the test continued (whereas the test would have been stopped in the original version).

The score is calculated out of 28, i.e. by selecting the item set 1-28.

2. Next, use the correspondence table to determine the ability score from the raw score based on the “item set” determined for the child:

PICTURE SIMILARITIES				
Raw Score to Ability Score				
Raw Score	Item Set			
	1-23	1-28	1-33	11-33
0	10 (15)	10 (15)	10 (15)	22 (15)
1	10 (11)	10 (11)	10 (11)	30 (11)
2	11 (8)	11 (8)	11 (8)	38 (8)
3	17 (7)	17 (7)	17 (7)	43 (7)
4	22 (7)	22 (6)	22 (6)	48 (6)
5	26 (6)	26 (6)	26 (6)	51 (6)
6	29 (6)	29 (6)	29 (6)	55 (6)
7	33 (6)	32 (6)	32 (6)	58 (5)
8	36 (6)	36 (5)	36 (5)	60 (5)
9	39 (5)	38 (5)	38 (5)	63 (5)
10	42 (5)	41 (5)	41 (5)	66 (5)
11	45 (5)	44 (5)	44 (5)	68 (5)
12	48 (5)	47 (5)	47 (5)	71 (5)
13	50 (5)	49 (15)	49 (5)	73 (5)
14	53 (5)	52 (5)	52 (5)	76 (5)
15	56 (5)	55 (5)	54 (5)	79 (5)
16	59 (6)	57 (5)	57 (5)	82 (5)
17	62 (6)	60 (5)	59 (5)	85 (6)
18	66 (6)	62 (5)	62 (5)	88 (6)
19	70 (6)	65 (5)	64 (5)	92 (6)
20	74 (7)	68 (5)	67 (5)	97 (7)
21	79 (8)	70 (5)	69 (5)	103 (8)
22	87 (11)	73 (5)	71 (5)	111 (11)
23	95 (15)	76 (6)	74 (5)	119 (15)
24		79 (6)	76 (5)	
25		83 (7)	79 (5)	
26		89 (8)	82 (5)	
27		96 (10)	85 (6)	
28		104 (14)	89 (6)	
29			92 (6)	
30			97 (7)	
31			103 (8)	
32			111 (11)	
33			119 (15)	

3. Last, use the ability score to percentiles correspondence table (tables available from Marie Cheminat). The scores were determined using a sample of 1,689 children aged 2 years 6 months to 17 years 11 months (814 boys, 875 girls) living in the United Kingdom. Data on ethnicity, mother tongue, educational level (father and mother), number of siblings and child's birth order in this sibship were collected from parents to ensure sample representativeness. Data on the region and school are also available.

5.3 Explanatory letter, accelerometry

We would like to measure your child's physical activity and sleep as accurately as possible. So that we can do this, we invite you to fill in the enclosed diary and fit your child with two accelerometers. This document explains what the accelerometers are, and how they are used.

1) What is an accelerometer?

An accelerometer is a small lightweight appliance that measures all your child's movements. To get more precise and accurate measures of physical activity and sleep, we use two accelerometers. One is worn around the waist to measure physical activity, and the other on the wrist to measure sleep.

The two appliances contain three microplates that rub against each other as your child moves. The movements of each microplate are recorded on a microchip. The appliance is powered by a flat battery like the one inside a watch. Do not open the appliances. There are no buttons or counters.

Remember that they are valuable items and expensive to replace.

2) How should they be worn?

The accelerometers must be worn for 7 consecutive days.

* The sleep accelerometer (watch) should be worn

- On the left wrist
- For 7 days and nights
- There is no need to remove it once the child has it on
- Your child can take a bath or shower, or go to the swimming pool with the appliance on their wrist.

* The physical activity accelerometer (red box on an elastic belt)

- It must be worn against the skin or over an undershirt or T-shirt (never over top clothes like coats).
- It must be placed over the right hip (above the hip bone).
- The belt must be tight but comfortable to wear. It must not be loose.
- The appliance must not move around or swing against your child's body, but follow his/her movements.
- The accelerometer should be put on when the child wakes up in the morning and removed at bedtime. There is no need to remove it for daytime naps.
- Important: the accelerometer must be removed when the child takes a shower or bath, and for all aquatic activities (swimming pool, etc.) as it is not waterproof. Please put it back on when the child is no longer in the bath, shower or swimming pool and leave it on until bedtime.

3) What will be done with the recorded information and the completed diary?

The information collected will be entered into a computer and made anonymous by authorized persons. It will remain totally confidential. It will then be analysed to measure the physical activity and sleep of children aged 3.5 years in France.

4) Will I be told about this information?

The analysed information is anonymous, so we will not be able to send you any personalized results, but we will send you the overall findings.

5) How can I find out more about this part of the Elfe study?

If you have any questions or would like more information about the appliances and the study, please contact xx xx xx xx (toll-free number).

Thank you for your help.

5.5 Information letter for teacher, accelerometry

Dear Sir or Madam,

The child

..... is taking part in the Elfe national child cohort, the first French longitudinal study that follows children from birth to adulthood and covers multiple social, health, and environmental health aspects of children's lives (<https://www.elfe-france.fr/>).

His/her parents have authorized him/her to take part in a specific study of sleep and physical activity measured objectively by accelerometers worn by the child for 7 consecutive days.

An accelerometer is a small lightweight appliance that measures all the child's movements. To get more precise and accurate measures of physical activity and sleep, we use two accelerometers. One is worn around the waist to measure physical activity, and the other on the wrist to measure sleep.

The two appliances contain three microplates that rub against each other as the child moves. The movements of each microplate are recorded on a microchip. The appliance is powered by a flat battery like the one found inside a watch. Do not open the appliances. There are no buttons or counters.

The accelerometers must be worn by the child during the afternoon nap. However, the accelerometer around the child's waist (red box) must be removed for aquatic activities (swimming) as it is not waterproof.

Remember that these appliances are valuable items and expensive to replace.

5.6 Accelerometry consent form

From Mr, Mrs or Ms (*name, first name*)

as father / mother (delete as appropriate) of (*child's name, first name*)

I have read the information brochure sent to me by mail concerning the physical activity and sleep study conducted as part of the Elfe project research programme, organized jointly by the National Institute for Health and Medical Research (INSERM) and the French Institute of Demographic Studies (INED).

I have read and understood the information about the purpose of this specific study that forms part of the child's follow-up.

I clearly understand that I am free to agree or to refuse for my child(ren) to take part in this specific study of the Elfe project and that this will not affect my continued participation in the Elfe project.

All the information recorded for this specific study will remain strictly confidential and will be analysed for research purposes only. These data will be recorded in a confidential (anonymized) computer file, in accordance with the rules laid down by the French data protection act (Loi informatique et liberté). I am aware that I have the right to check the accuracy of the information I have given and that I can ask for it to be corrected or destroyed by sending a request to Dr Marie-Aline Charles, Director of the Elfe research unit, 133 Bd Davout, 75980 Paris Cedex 20.

If you agree for your child to take part in this secondary study of the Elfe project and authorize all or part of the data collected for this study to be transmitted to the scientists of the Elfe research unit, please indicate your agreement below by ticking the relevant boxes.

- › I agree for my child to take part in the study on physical activity and sleep. This involves the transmission of data collected by the accelerometers and the diary to the various bodies involved in following up the Elfe project children

YES NO

By giving my consent, I do not release the Elfe project organizers from their liabilities and I maintain all my rights under French law.

I am free to decide to withdraw my child from this specific study at any moment, without providing any justification, in which case I agree to return the appliances to you.

I undertake to inform the other parent with parental authority that I agree for our child to take part in the secondary study, and to give him/her the form which he/she can use if necessary to indicate his/her refusal for the child to take part.

Signed (*in duplicate*) at (place)

Date (*day, month, year*):

Signature:

If you would like further details or additional information about the Elfe project, you can contact the study coordinators by calling the toll-free number

or you can consult the Elfe website: <https://www.elfe-france.fr>

*To be completed by the interviewer:
Interviewer's name, forename
Date*

5.7 Sample information form

Please use this form to record all information concerning the samples collected from your child. This information form must be returned with the samples. After it has been filled in, place it in the sample shipment box.

The Elfe team wishes to thank you once again for taking part in this study.

Urine and hair samples can be collected on **Sunday morning, Monday morning, Tuesday morning or Wednesday morning**.

They must be **sent back** as soon as possible, **24 hours at most** after they have been collected.

Important: Do not send them back on a Thursday or Friday as the laboratory is closed at the week-end and the samples will become more difficult to analyse. So please send back the samples on **Monday, Tuesday or Wednesday**.

ID code

SAMPLE COLLECTION:	To be completed by the family
<p>urine: yes <input type="checkbox"/> no <input type="checkbox"/></p> <p>collection date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 2 0 time: <input type="text"/> <input type="text"/> h <input type="text"/> <input type="text"/> min</p> <p>hair: yes <input type="checkbox"/> no <input type="checkbox"/> hair too short (less than 2 cm) <input type="checkbox"/></p> <p>sample collection date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 2 0</p>	To be completed by the family
<p>SAMPLE DELIVERY</p> <p>EFS CENTRE:</p> <p>Reception date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 2 0 time: <input type="text"/> <input type="text"/> h <input type="text"/> <input type="text"/> min</p> <p>urine:</p> <p>storage date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 2 0 time: <input type="text"/> <input type="text"/> h <input type="text"/> <input type="text"/> min</p>	
<p>OBSERVATIONS AND NON-CONFORMITIES:</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>	

To be completed by EFS

IMPORTANT INFORMATION

The evening before you took the urine sample, what time did your child go to the toilet for the last time before going to bed? |_|_| h |_|_| min you don't know

Before you took the urine sample, was your child wearing a nappy? yes no

→ If yes, was the nappy wet when the child woke up? yes no you don't know

→ If no, did your child go to the toilet in the night? yes no you don't know

→ If yes, at what time? |_|_| h |_|_| min

The evening before you took the urine sample, what time did your child have his/her evening meal?

|_|_| h |_|_| min you don't know

The evening before you took the urine sample, did you use on your child:

Shower gel? yes no

Shampoo? yes no

Body lotion or cream? yes no

Perfume or toilet water? yes no

Composition of evening meal preceding urine sample collection

Type of food*	Packaging						Place of eating (and preparation)				Type of cooking or reheating					
	Plastic or plasticized paper	Glass	Tin can	None	Other	Don't know	Home	Restaurant	Fast-food restaurant	Other	Plastic container in microwave oven	Glass container in Microwave oven	Non-stick pan	Oven	None	Other
Example:																
Crisps	x						x									x
Soup					x		x				x					
Oil		x					x								x	
Pasta					x		x									
Mineral water	x						x								x	

*Include drinks and condiments = tap water, bottled water, fizzy drink, etc.

5.8 Biological sample consent form



1st child

2nd child, if twins

Mr/Mrs/Ms (*NAME, relationship to child*)hereby certify that I have read and understood the information letter given to me by the Elfe team. I was able to ask as many questions as I wished and was given enough time to consider before deciding to contribute to the biobank (or biological sample bank) of the Elfe study research programme.

I am fully aware that I am free to agree or to refuse the request for biological samples to be collected from my child(ren) (urine, hair, stools) and stored at the Elfe project biobank.

When the samples are collected, they will be "anonymized" (coded) and stored in the Elfe biobank for use in biological analyses performed for research purposes only. They may, for example, be used to measure the presence of environmental pollutants or infectious agents. The purpose of these biological analyses is to find out whether exposure to certain factors during the first years of life affects the child's subsequent health and development.

The biological and DNA samples will be stored in the biobank for a period of 10 years from the date of signature of the present consent form. At the end of this period, a request to extend the period of sample storage for a further ten years will be submitted to the relevant ethical and legal authorities. This request will be renewed every 10 years.

All results of measurements and analyses conducted for the Elfe project will remain strictly confidential and will be used for research purposes only. These data will be recorded in a confidential (anonymized) computer file, in accordance with the rules laid down by the French data protection act (Loi informatique et liberté).

I have also been informed that I can terminate at any time my participation in the Elfe biobank and request the destruction of the biological and DNA samples concerning my child(ren) by sending a letter to Dr Marie-Aline Charles, Director of the Elfe research unit, 133 Bd Davout, 75 980 Paris cedex 20.

This biological collection procedure has been approved by the Comité de Protection des Personnes of Île-de-France IX.

If you agree to contribute to the Elfe biobank and to allow all or part of the biological material collected to be used for research purposes under the conditions stated above, please give your consent by ticking the relevant boxes:

➤ I give my consent for the biological samples collected from my child(ren) to be conserved and used for specific biological analyses at the Elfe biobank.

YES

NO

By giving my consent, I do not release the Elfe project organizers from their liabilities and I maintain all my rights under French law.

Signed (*in duplicate*) at (place)

Date (*day, month, year*):

Mother's/father's signature:

If you would like additional information about the Elfe project, you can contact the study coordinators by calling 01.56.06.21.01 or by sending an email to communaute@elfe-france.fr

5.9 Vacuum cleaner dust sample collection protocol

For homes with bagless vacuum cleaners we will send instructions to the parents to clean out the dust chamber at a specific time t and to use the vacuum cleaner without emptying the dust chamber for the same length of time as homes having vacuum cleaners with bags, and we will provide a container to collect the dust chamber contents.

In terms of protocol, participants will be asked to avoid vacuuming certain rooms, such as the bathroom, if possible. Participants will be asked to complete a sample collection sheet and a qualitative questionnaire to describe the rooms in the home and the family's living habits. A postage-paid box will be provided for dust sample shipment.

- Vacuum cleaners with bag

- Remove the vacuum cleaner from its storage place in the home
- Prepare a zipped bag and place it nearby
- Put on gloves and a protective mask
- Open the vacuum cleaner cover to access the bag (referring to the user's manual if necessary, or following the owner's instructions)
- Remove the bag carefully without letting any dust escape
- Place the bag carefully in the zipped bag, again without letting any dust escape
- Reclose the zipped bag
- Identify the sample by placing an adhesive label on the zipped bag
- Put the vacuum cleaner away, clean up if necessary with a dustpan and brush, and place any spilled dust and the rubber gloves in the small blue dustbin bag

- Bagless vacuum cleaners

- Remove the vacuum cleaner from its storage place in the home
- Prepare a zipped bag and place it nearby
- Put on gloves and a protective mask
- Open the vacuum cleaner cover to access the dust chamber (referring to the user's manual if necessary, or following the owner's instructions)
- Remove the dust chamber carefully without letting any dust escape
- Cover the dust chamber completely with the opened zipped bag
- Empty the dust chamber as carefully as possible without letting any dust escape until the entire contents have been emptied into the zipped bag
- Wait for around two minutes to allow the dust to settle
- Gently remove the dust chamber and close the zipped bag
- Identify the sample by placing an adhesive label on the zipped bag
- Put the vacuum cleaner away, clean up if necessary with a dustpan and brush, and place any spilled dust and the rubber gloves in the small blue dustbin bag

- Information on collected dust sample

On the sample information form, note down all information relative to the dust collected (vacuum cleaner with/without bag, collection date, time since bag was changed or dust chamber emptied, rooms habitually vacuumed, vacuum cleaner used in garage or basement, car interior, fireplace or stove, DIY (sawdust, plaster, debris...) vacuum cleaner used outside (balcony, terrace, etc.).

- Sample shipment to the laboratory

Place the zipped bag in an opaque black dustbin bag to protect it from light and then in the shipment box that must be posted the same day.

Protocol for dust collection with cloth wipes

- The sample is taken on the most suitable area of floor (depending on the most areas most frequently occupied, the work carried out, or otherwise the centre of the room). If there are several types of flooring, a sample is taken from each different type.

Note on the sample information form:

- the specific area(s) in the room where samples were taken
- the type of flooring where the sample was taken
- approximate room size

To avoid any risk of sample contamination during collection or shipment, the following procedure must be scrupulously followed:

- Wear new gloves, wipe the template with a clean cloth
- Place the template on the floor where the sample is to be taken
- Unfold a clean cloth and place it inside the template
- Place the flat of your hand on the cloth and press down firmly.

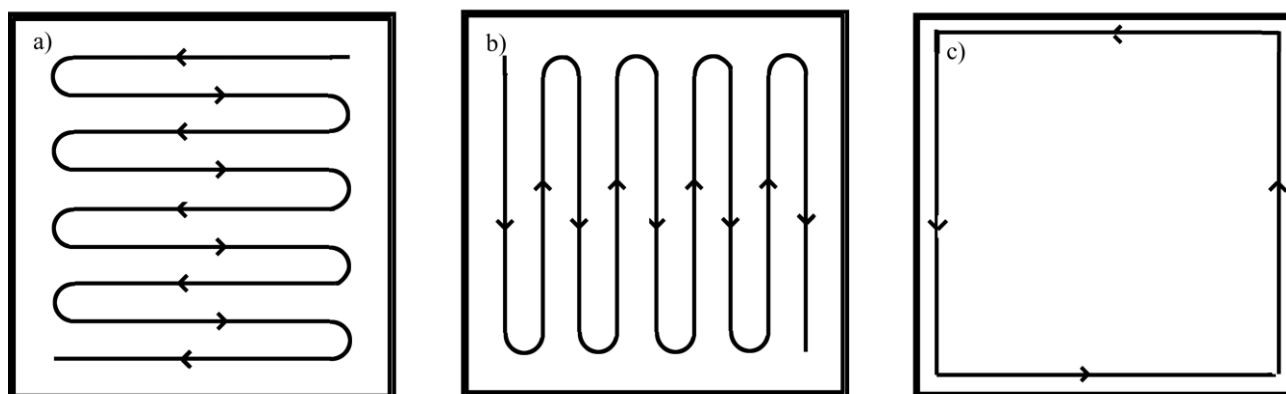


Figure 1. Three-stage sample collection

- Wipe the cloth over the floor in an S-shaped pattern as shown in Figure 1a until the entire surface to be sampled has been covered
- Fold the cloth in half so that the contaminated surface is on the inside (take care not to touch the contaminated part when folding the cloth)
- Wipe the cloth over the floor in the same S-shaped pattern as before, but in a perpendicular direction (Figure 1b)
- Fold the cloth a second time as described above
- Wipe the cloth around the edge of the template (Figure 1c)
- Fold the cloth into three lengthwise, roll it up and insert it into the brown glass tube labelled with the sample ID number
- Seal the tube and label the sample (building, room and location inside room if several samples taken in one room).

A control sample is produced on each sampling site. To do so, on each sampling site, place a cloth wipe folded as described above into a brown glass tube, then seal and label it.